

University of Minnesota Human Subjects Research Requirements

Student research assistants in a CURA program (NPCR, CAP, or Communiversities) should be aware that their research may involve human subjects. At the University of Minnesota, human subjects' research is overseen by the Institutional Review Board (IRB) to ensure that projects meet institutional and ethical standards for the protection human subjects. The IRB administration and CURA have worked together to ensure that these standards are being met. What follows is a guide to the CURA/IRB relationship.

What is human subjects research?

Human subjects research involves collecting and/or analyzing data from people. In a CURA project, human subjects research is involved if the research assistant is conducting focus groups, surveys, or interviews; reviewing reports of focus groups, interviews, or surveys conducted by others; or working with information from an organization's client database.

What are the issues and concerns for human subjects research?

Although there are a number of legal regulations and ethical guidelines concerning human subjects research, the IRB has two broad standards:

- ▶ subjects must not be placed at undue risk, and
- ▶ subjects must give uncoerced, informed consent to their participation.

Another set of guiding principles for human subjects research comes from the *Belmont Report*, which was released by the U.S. Department of Health, Education and Welfare in 1979. The *Belmont Report* identifies three core values for human subjects research:

- ▶ respect for persons: all individuals have autonomy;
- ▶ beneficence: all potential risks and benefits to individuals must be weighed; and
- ▶ justice: no population should bear undue risk from research if they will not also share in the benefits.

The Institutional Review Board website has links to the regulations and ethical considerations involved with human subjects research, including the Code of Federal Regulations and the Belmont Report. Visit www.irb.umn.edu/regs.cfm

The website also contains an online tutorial on informed consent and several sample consent forms, including some translations. Visit www.irb.umn.edu/consent/.

Finally, the website has information about data privacy and confidentiality. Visit www.irb.umn.edu/topics/hipaa. (See item #7, "Using Data that is De-Identified.")

Privacy and confidentiality are other major concerns. Information that personally identifies a research subject, or makes it easy for others to identify him or her, must not be included in project reports that will be available to the public. Researchers, of course, also should not share information about their subjects with others outside of the research project.

Does my CURA project need to be reviewed by IRB?

The Regents of the University of Minnesota have established a policy for determining when a project must be reviewed by IRB:

- ▶ if the research is being done by a University student, staff member, or faculty member;
- ▶ if the research involves data collection or data records of human subjects; and
- ▶ if a student researcher is using the research to fulfill graduation or degree requirements.

Although many CURA projects meet the first two criteria, the IRB has determined that most CURA projects do not require IRB review. This is because students working on CURA projects, although employed by the University of Minnesota, are really doing their work for an outside organization. This means that CURA research assistants are generally conducting research as a job for an employer, so the employer is responsible for ensuring the safety and obtaining the consent of the research subjects.

How do I know if my CURA project needs to be reviewed by IRB?

There are two circumstances in which a CURA project may require further consideration by IRB:

- ▶ if the human subjects belong to a population that would be considered “vulnerable”;
or
- ▶ if, in addition to conducting the research for the community organization, you also plan to use the data you gather in a course paper, a thesis, a journal article, or some other academic application.

At the beginning of each semester and each summer, CURA staff send descriptions of our projects to the IRB to identify any projects that might warrant further consideration by the IRB. The IRB can ask CURA for more information about a project, even if the student research assistant is not planning to use the research for an academic purpose. When the IRB expresses concern about a project, CURA staff provides the IRB with additional information about how the research will be conducted, who will be supervising the research, what qualifications they bring to the work, and so on to build all parties’ confidence that the project will be handled professionally and ethically.

Projects Involving Vulnerable Populations

One of the IRB’s concerns has to do with projects involving a vulnerable population, such as children, the disabled, people of color, people living in poverty, undocumented workers, etc. Even in these cases, however, a project may not require IRB review. If the research questions are about a program serving the vulnerable population, rather than individuals, it probably will not need IRB approval; as a general rule, program evalu-

To learn more about working with vulnerable populations, visit www.irb.umn.edu/training/. This part of the IRB website also has many other informative and helpful training modules.

ations an organization conducts to assess its effectiveness and improve its services do not require review. The same is true if a research assistant is analyzing data that the organization has already gathered and the organization has deleted all personally identifying information about the participants. If a research assistant is working with personally identifiable information about specific individuals and the IRB determines that the project will require the submission of an application for prospective review, CURA staff will work with the student and the community organization to make sure sufficient time is allowed for this process and to assist in any way we can.

Using Research from a CURA Project for Academic Purposes

A student will always need to submit an application to the IRB for a project if he/she decides that besides providing the requested information to the community organization, he/she would like to incorporate the research conducted through a CURA assistantship into an academic project. This guideline applies whether the student knows at the beginning of a CURA project that they plan to use the research for an academic purpose, or whether they decide to do so sometime after completing the CURA project. If a student decides later to use the project for an academic purpose, he/she can probably apply under “exempt category 4,” for use of existing data.

To learn how to apply for IRB review, visit www.urb.um.edu/studentResearchers/. Also visit www.urb.um.edu/applying/ for descriptions of the three levels of review: exempt, expedited, and full.

If a student knows at the beginning of a CURA project that they plan to use the research for an academic purpose, they should be aware that because CURA views its research assistants as employees of the community organization, any academic use students make of CURA-sponsored research is considered to be the student’s own pursuit (that is, it is not part of what the community organization has hired the student to do for them) and thus will not be compensated by CURA. This includes the time it takes to secure IRB approval for the project. However, to keep community work from being delayed while a student seeks IRB review for an academic project, CURA staff will be happy to help facilitate the process in any way we can.

What if a student research assistant is not comfortable with the way a community organization is handling the research?

Although the community organization, as the student’s “employer,” is considered to have primary responsibility for how the research is conducted, student research assistants should still be aware of and committed to the standards of human subjects protection. CURA staff believe students should never have to compromise their ethics as part of their CURA job. If a student is uncomfortable with how the organization is conducting the research or has concerns about participants’ privacy, protection from risk, level of consent, or knowledge of how the information they provide will be used, the student’s first step should be to talk to his or her community supervisor. If the supervisor is not responsive to the student’s concerns, the student should contact the coordinator of the CURA program sponsoring their research assistantship (see contact information below). CURA staff will work with the student and community supervisor to achieve a positive resolution, if at all possible. Students may also contact the IRB with questions about research ethics and they will assist in any way they can.

What if, while doing research, a student receives sensitive information relating to abuse, neglect, or criminal activity?

As a general rule, part of protecting the human subjects involved in research includes keeping their information confidential and making sure that information about their personal lives and activities will not be used “against them” in any way. Students are not obligated to report any criminal activity they hear about in their work at CURA—and they may not want to if doing so might harm their research subjects.

In cases of abuse, neglect, or maltreatment of a child or a vulnerable adult, however, a student may want to tell someone who is in a position to help the victim. If a student thinks this subject could

come up during his or her CURA project, he/she should talk to the community supervisor early in the project about how to handle these situations; the supervisor or someone else in the organization may be required to report suspected abuse or neglect under state law. The Minnesota Department of Human Services (DHS) website also provides information on how to report such cases to appropriate authorities. An individual’s identity as the reporter is kept confidential by the investigating agencies.

For information on reporting cases of child abuse or neglect, or maltreatment of a vulnerable adult, visit www.dhs.state.mn.us.

Questions? Contact one of the following individuals:

Kris Nelson, NPCR Program Director, 612-625-1020 or ksn@umn.edu

Will Craig, CAP Program Director, 612-625-3321 or wcraig@umn.edu

Jeff Corn, Communiversity Program Coordinator, 612-625-0744 or jcorn@umn.edu

Jeffery Perkey, IRB Liaison to CURA, 612-626-5922 or perke001@umn.edu